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EXAMINER

FERNANDEZ, SUSAN EMILY

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/576,298	Applicant(s) KORPELA ET AL.	
	Examiner SUSAN E. FERNANDEZ	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16,37 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16,37 and 38 is/are rejected.
- 7) ☒ Claim(s) 1-16,37 and 38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/17/08</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment filed October 29, 2010, has been received and entered.

Claims 17-36 are canceled. Claims 37 and 38 are new. Claims 1-16, 37, and 38 are pending.

Election/Restrictions

Applicant's election of Group I, claims 1-16, 37, and 38, in the reply filed on October 29, 2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, and the claims drawn to the other invention (claims 17-36) are canceled, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-16, 37, and 38 are examined on the merits to the extent they read on the elected subject matter.

Claim Objections

Claims 1-16, 37, and 38 are objected to because of the following informalities:

At least claims 1-3, 7-10 and 12 refer to the reactor vessel as reference numbers 26 and 61. While not so egregious so as to render the claim indefinite, it would be simpler to refer to just one reference number, i.e. just 26, as it is clear that reference is being made to the reaction vessel. All other claims inherit the deficiency of at least claim 1 or 3, and thus are objected to for the same reason.

Also, claim 1 is objected since the term "the" prior to "controlled conditions" in the second line of step (b) of claim 1, should be deleted.

Claim 3 is also objected as the recitation "biological component" in the third line of step (a) should be replaced with "biological components."

Claims 2 and 4-16 are also objected to because the term "A" at the beginning of each of these claims should be replaced with "The."

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Finally, claim 38 is objected to as the recitation “*Escherichia coli* H7:O157” is the improper name for the known strain “*Escherichia coli* O157:H7.”

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16, 37 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the fact that the micro particles (22) are magnetic. Currently neither of claims 1 or 3 define the micro particles as being magnetic, without such property it would not be possible to collect the desired biological components bound to the micro particles via the magnetic unit (10). Correction is required.

Claims 1-16, 37, and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, step (b) requires the micro particles to bind to the biological component in the solution; however, it is not clear that there are biological components *in the solution*. It is noted that step (a) merely requires placement of micro particles that bind to a desired biological component into a solution, this is interpreted as requiring the micro particles *to be capable of* binding to a desired biological component, but does not require the same desired biological components to be present *in* the solution. Each of claims 2, 4-16, 37 and 38 inherit the deficiency of claim 1 and thus are rejected on the same basis.

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For purposes of applying prior art the claim will be interpreted as though the desired biological components are present within the solution.

Also in claim 1, there is insufficient antecedent basis for the limitation "the controlled conditions" in the fifth line of the claim.

Claim 3 is rendered indefinite by the recitation "magnetic synthesis...of biological components" in the preamble because the definition of the term "magnetic synthesis" is unclear.

Step (a) also refers to the "biological component to be synthesized." However, it is unclear from the steps recited how synthesis of biological components occurs. Moreover, as the solution already comprises the "biological component to be synthesized," it would appear that synthesis already took place prior to step (a).

Also in claim 3, the recitation "proper activity and/or binding properties" in the first two lines of step (a) is confusing. It is unclear what activity and binding properties would be deemed "proper," or for which purposes are they "proper." The recitation "if needed" in the second line of step (b) also renders the claim indefinite since it is unclear whether the step of mixing is a required limitation. Moreover, it is unclear what is judged to determine the need for mixing (needed for what purpose?).

Additionally, claim 3 is rendered indefinite by the recitation "a desired reaction and/or binding reaction" in step (c) since it is unclear how these reaction(s) relate to the synthesis/binding/isolation/purification/enrichment of the biological components. It is unclear what characteristics would be required to deem a reaction "desired."

Finally, claim 3 is indefinite since it is not clear that any synthesis, binding, isolation, purification, or enrichment of biological components occurs. No steps are provided to indicate that the biological components are synthesized, bound, isolated, purified, or enriched. Moreover, it is unclear how the micro particles relate to the biological component recited in step (a). It would appear that the micro particles bind to the biological components, and that additional steps are required to isolate, purify,

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and enrich the biological components. Claims 4-16, 37 and 38 depend from claim 3 and thus inherit the deficiencies of claim 3, and therefore are rejected under 35 U.S.C. 112, second paragraph.

Claims 4, 7, and 8 are indefinite when depending from claim 3 as the recitation “the closed reactor unit (60)” lacks antecedent basis. Parent claim 3 does not refer to any “closed reactor unit” but simply refers to “a reactor unit (60).”

Claim 7 is indefinite when depending from parent claim 3 since claim 3 does not recite that the biological components were ever bound to the micro particles. Therefore, there is lack of antecedent basis for the recitation of the biological components bound to micro particles.

Claims 13-16 are indefinite since it is unclear how they relate to the steps of parent claims 1 or 3. It is unclear how they relate to the enrichment of the desired biological component of claim 1, or to the synthesis, binding, isolation, purification or enrichment of the biological components of claim 3. Thus, claims 13-16, 37, and 38 are rejected under 35 U.S.C. 112, second paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 38 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitation of “*Escherichia coli* H7:O157” in claim 38 is considered new matter. The specification supports “*Escherichia coli* O157” (page 20, line 29), but not “*Escherichia coli* H7:O157.” Because the specification as filed fails to provide clear support for the new claim language, a new matter rejection is clearly proper.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7, 9, 13, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Tuunanen (US 6,040,192. Listed on 11/17/08 IDS).

Tuunanen discloses a method for determining the presence of an analyte in a sample (claim 1) which is suitable for various purposes, such as immunologic, DNA-hybridization or hormone determinations (column 2, lines 35-36). Figure 1 demonstrates the apparatus for immunodetermination (column 3, lines 48-49). A sample to be examined is inserted into a first well (2) containing a suitable diluter in plate (1), which further comprises other wells (column 4, lines 4-5). Magnetic particles (8) coated with a desired separating reagent (immunologic substance, which have a binding property/activity towards the analyte to be detected) are also brought into the well (column 4, lines 5-7). These magnetic particles are microparticles (column 2, lines 46-48). The desired separating reagent of the magnetic particles reacts to form a complex with the analyte (in the sample) to be determined (column 3, lines 56-58). Therefore, the process of Tuunanen teaches the steps of placing microparticles that bind to a desired biological component (analyte contained in the sample) into a solution (diluter) containing the biological component (analyte) in a reactor vessel (well 2), and then allowing the microparticles to bind to the biological component (analyte) in the solution.

A remover (3) is also brought into the first well (2) (column 4, lines 5-7). The remover has a bore (9) containing a movable pin (1) provided with a magnet (10) (column 3, lines 58-59). The wells are preferably closed with a film which is punctured by the remover (column 2, lines 66-67 and column 3,

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lines 1-2). Therefore, the system as a whole is considered a closed reactor unit, and is under controlled conditions. See also column 2, lines 52-56 and column 3, lines 54-55, which teach that the mass transfer and necessary reaction time in the well are controlled by the vertical movement of the remover, and thus the conditions of the reactor vessel are considered to be 'controlled.' Also, the temperature is controlled as the equipment may have a thermostatic heater for keeping the plates at a desired temperature (column 5, lines 27-28). Also, because the remover is moved in the well to promote blending (column 4, lines 11-12 and column 3, lines 2-3), the step of moving the remover into the well to promote blending reads on mixing the microparticles in the solution in the reactor unit. Therefore, Tunnanen teaches that the binding of the microparticles with the desired biological component occurs in a solution in a closed reactor unit under controlled conditions, wherein the closed reactor unit comprises a magnetic unit (the remover 3) comprising at least one magnet (the magnet 10) and the reactor vessel (first well 2), and wherein conditions in the closed reactor unit are controllable.

When the binding reaction is occurring to form an immunocomplex, the movable pin (1) may be in the upper position (column 4, lines 7-11). After incubation, the magnet is moved to the lower position such that the particles (the immunocomplexes comprising the magnetic particles bound to the analyte) gather onto the remover surface (column 4, lines 12-15). Therefore, the reference discloses using the magnetic unit (the remover 3) to collect the desired biological component bound to the microparticles (immunocomplexes) in the solution in the closed reactor unit. Thereafter, the remover with the attached particles are moved into a second well and released into the second well to perform washing or a tracer reaction (column 4, lines 13-16). The second well contains a washing fluid (column 4, lines 54-55) and the remover can be of such a design that when the remover is in the second well, the pin is pulled up, whereby the particles will again blend with the medium (the fluid in the second well) (column 4, lines 52-54). Clearly this is a teaching of the release of the particles into a solution of another vessel (as required by instant claim 2). Given that the analyte in a solution is removed from other components in a solution

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in the first well, and then placed in a second well with a washing solution, there is indeed isolation, purification, and enrichment of the analyte. Therefore, Tuunanen anticipates instant claims 1-3, 7, 9 (moving the remover in relation to the walls of the well; pumping the solution inside the well by the vertical movement of the remover), claim 13 (since the method of Tuunanen is contemplated for DNA-hybridization, the immunologic substance on the microparticles may bind to DNA) and claim 16 (again, since the method is contemplated for DNA-hybridization).

Furthermore, instant claim 4 is anticipated as the magnetic particles attach to the remover, thus forming a thin layer over the magnet unit (the remover), and since the remover itself can have a sheath (4) (column 3, lines 50-51), which can read on a protective membrane, the magnetic particles forming a thin layer over a protective membrane (sheath 4) of the magnet unit (the remover).

Tuunanen also teaches that the separating reagent coated onto the magnetic particles (immunologic agent) can be an antibody (column 1, lines 56-57), thus meeting the limitation in instant claim 13 that an antibody is bound to the surface of the micro particle.

A holding of anticipation is clearly required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of

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each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-16, 37, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tuunanen in view of Ekenberg (US 5,567,326. Listed on 11/17/08 IDS).

As discussed above, Tuunanen anticipates claims 1-4, 7, 9, 13, and 16. However, Tuunanen does not expressly disclose that the first well comprises channels for rotating the solution comprising the sample in and out of the first well, for adding or removing the sample from the first well, for controlling the gases/liquids added into the first well, for controlling pH value and salt content in the first well, or for filtering the gases/liquid added into the first well. However, MPEP 2144.04, Section III indicates that "...broadly providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art." In the instant case it is submitted that inclusion of a channel to send the sample and the diluter into the first well of Tuunanen would have been obvious to the person of ordinary skill in the art since it would have provided automation of the manual activity of introducing the sample and the diluter into the first well. As the sample/diluter is introduced, the pH value and salt content is indeed changed. Therefore, the channel is for controlling pH value and salt content in the first well. Moreover, see column 6, lines 1-2, which teaches a sample dosing pump. It would have been obvious that the pump comprises a channel leading into the first well for sample introduction. Thus, instant claim 5 is rendered obvious.

Tuunanen also differs from the claimed invention in that while they teach moving the remover so as to promote blending (agitation) of the sample and magnetic particles, they do not expressly disclose that the agitation within the first well is by: (1) movement of projections or depressions inside the outer surface of the first well, (2) rotation of the apparatus around its longitudinal axis or by rocking the

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apparatus, (3) movement of a flexible element in the remover, (4) pushing the bottom of the first well (comprising a stretchy material) downwards, or (5) rotation of the remover (thus rotating the magnets). However, Tuunanen points out that agitation of the medium can alternatively be promoted by a suitable remover and vessel design (column 2, lines 60-61). Therefore, it would have been obvious to have agitated the contents of the first well by other means, including those means listed above, since there would have been a reasonable expectation of success in agitating the medium by these remover and vessel designs. Modification of the reactor vessel (well) so as to accommodate different samples and/or magnetic particles would have been a matter of routine experimental design choice. Selection of appropriate vessel designs which have the various agitation properties as claimed would have been *prima facie* obvious to one having ordinary skill in the art, as the ultimate effect (mixing of the sample and magnetic particles to improve contact between the remover and the magnetic particles to permit attraction and binding for removal) would be the same. Therefore, instant claims 8 and 10-12 are rendered obvious.

Furthermore though Tuunanen teaches that the wells are placed in an environmental cabinet that controls the temperatures of the reactor units (see Figure 3 and column 5, lines 10-12, 27-28) and controls the sampling and additions of samples or solutions into the wells (column 5, lines 30-31), Tuunanen does not teach that the environmental cabinet controls the rotation speeds of the magnets or the gas exchange. However, as discussed in the previous paragraph, it would have been obvious to have rotated the remover (comprising the magnets) to agitate the medium. It then would follow that it would also have been obvious to have controlled the rotation speed of the remover (and thus the magnets of the remover) in the environmental cabinet since the skilled artisan would have expected that the agitation of the medium is dependent on the rotation speed (the greater the rotation speed, the greater the amount of agitation). Furthermore, it would have been obvious to control the gas exchange in the environmental cabinet since Tuunanen indicates that the vessels (the wells) may contain an inert vapour phase to improve durability

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(column 3, lines 7-8). As the gas phase affects the durability, it would have been obvious to have controlled it to a level that is for optimal durability. Therefore, instant claim 6 is rendered obvious.

Tuunanen also differs from the claimed invention in that it does not expressly disclose that the analyte being detected (and thus isolated and enriched) is a pathological bacteria, virus, parasite, or protozoa.

Ekenberg discloses a method for separating biological substances of interest which involves the separation of magnetic particles from nonmagnetic media (column 5, lines 56-67). The magnetic particles comprise a receptor capable of binding the target substance of interest in the test sample (column 6, lines 11-14). See claim 11, which describes the method, wherein a test medium is introduced into wells and then the magnetically responsive particles are contacted with the target substance in the test medium. Pins are positioned within the wells and are then magnetized by a magnet pack (column 9, lines 32-35). The magnetically responsive particles (bound to the target substance) adhere to the pins, and then the pins are removed from the wells and immersed into a resuspension medium (claim 14). The magnetically responsive particles bearing the target substance then dislodge into the resuspension medium (claim 14). Dislodging the magnetically responsive particles into the resuspension medium facilitates analysis (column 10, lines 37-39). The target substances that are magnetically separated by the method of Ekenberg include cells, cell components, bacteria, parasites, proteins, viruses, specific nucleic acid sequences, DNA, and mRNA (column 6, lines 18-45).

Based on the teachings of Ekenberg it is submitted that, at the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have used the device of Tuunanen to separate (thus isolate and enrich) other biological substances, including bacteria, viruses, parasites, other cells such as protozoan cells, cell components, proteins, and specific nucleic acid sequences.

Alternatively, it would have been obvious to have practiced the Tuunanen method for determining the presence of analytes other than immunologic substances, including bacteria, viruses, parasites, other cells

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such as protozoan cells, cell components, proteins, and specific nucleic acid sequences. One of ordinary skill in the art would have been motivated to do this because Ekenberg has successfully demonstrated that magnetic particles can be used to separate these biological substances by binding the biological substances to the magnetic particles to create complexes which are then removed from the solution via the application of a magnetic field. Thus instant claims 15 and 38 (since obvious to isolate/enrich any bacteria/parasite/protozoan) are rendered obvious.

Further still, it would have been obvious to have used the separated magnetic particles bound to the biological substances to carry out chromatographic purification (ion exchange, reverse phase, hydrophobic, affinity) since purification by chromatography for detecting and analyzing biological substances is well known within the art, and techniques for performing such were well within the purview of the artisan of ordinary skill. Thus further modifying the method of Tuunanen to include an additional step of chromatographic purification of the separated biological components would have been *prima facie* obvious to one having ordinary skill in the art. Therefore, instant claims 14 and 37 are rendered obvious.

A holding of obviousness is clearly required.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN E. FERNANDEZ whose telephone number is (571)272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Allison M. Ford/
Primary Examiner, Art Unit 1651

Susan E. Fernandez
Examiner
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sef